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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,371	10/12/2000	Matthew Cotten	0652.2150001/EKS/PAJ	5877

7590 11/05/2002

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	19

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/688,371	COTTEN ET AL.
	Examiner	Art Unit
	Shanon Foley	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 August 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2,4-16 and 41-56 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 2,4-16 and 41-56 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

In paper no. 17, applicant cancelled claims 1, 3, amended claims 2, 4-8, 12, 13, 15, and added new claims 41-56. Claims 2, 4-16, and 41-56 are under consideration. The examiner appreciates the list of page and line numbers supporting the amendments to the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to derivatives of a plasmid, "pAIM65". However, the metes and bounds of what would be considered a "derivative" of the plasmid cannot be determined.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 4-16 and 41-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8, 16, 20-28, 30-34,

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81, 83, and 149-162 of U.S. Patent No. 6,335,016 for reasons of record. This rejection will be obviated once a terminal disclaimer is received.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2, 4, 5, 7, 8, 41-43, 45, 46, 55, and 56 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Michou et al. (Journal of Virology. Feb. 1999; 73 (2): 1399-1410) for reasons of record.

Michou et al. anticipates a the plasmid encoding the recombinant CELO virus is a pAIM plasmid and therefore, anticipates the pAIM65 “derivatives” recited in claims 55 and 56.

Claims 2, 4-16, and 41-56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baker et al. (WO 97/40180, translation provided in IDS of paper no. 13) for reasons of record.

Claims 2, 4-16, and 41-56 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Baker et al. (US 6,335,016) for reasons of record.

Both Baker et al. references anticipate new claims 55 and 56 because a derivative of the instant pAIM65 is presumed to be any plasmid that expresses a modified CELO virus with disrupted GAM1 expression that replicates in prokaryotic or eukaryotic cells. Both Baker et al. references teach a plasmid encoding a modified CELO virus that lacks the sequences necessary for GAM1 expression that is replicable in bacteria, yeast, or bird embryo kidney or liver cell lines, see the previous citations listed in the last Office action. Therefore, Baker et al. (WO '180 and US '016) anticipate pAIM65 derivatives.

Applicant disagrees that the teachings in the references anticipate any variation of deletions within the ranges taught. Applicant states that the disclosure of a genus does not anticipate a species within the genus, i.e. the references do not specifically encompass the specific deletions claimed that negatively effect Gam1 expression. Applicant argues that neither Baker et al. reference attempt to narrow the genus. While applicant admits on page 15 of the response that the Baker et al. references teach "that any or all of the nucleotides within the region can be deleted", the skilled artisan would be unable to immediately discern the instant CELO DNA in view of the number of possible deletions in either Baker et al. or Michou et al. Applicant concludes that the references do not disclose the invention with sufficient specificity to constitute anticipation.

Applicant's arguments and careful review of each reference has been considered, but are found unpersuasive to overcome the prior art rejections. It is maintained that one of ordinary skill in the art would envisage any specific range of nucleic acid deletions taught in the cited references. (Since the disclosures of Baker et al. are the same, Baker et al. '180 is cited to address arguments against both Baker et al. references for the purpose of convenience.) Contrary to applicant's assertion that Baker et al. does not anticipate limiting the range of deletions taught, Baker et al. specifically teaches that the virus "contains modifications which are located on a section of CELO virus DNA which comprises the nucleotides...from about 31,800 – about 43,734...", see claim 3 of the translation of WO 97/40180. This explicit teaching of the modifications within the regions anticipate any partial deletion of the entire region taught by Baker et al. anticipates all and every possible deletion therein. Michou et al. specifically teaches deletion of Gam1 within the deleted range, see figure 3 on page 1403. Therefore, it is apparent that the skilled artisan would be able to immediately envision smaller deletions taught by Michou et al. based on the information provided regarding right end open reading frames.

Applicant recited excerpts from the disclosure teaching that the instant deletions result in a loss of Gam1 expression, which renders the instant recombinant replication-defective. The recombinant CELO viruses of Michou et al. and Baker et al. encompass deletions spanning Gam1 and are taught to be replication-defective. Therefore, the viruses of Michou et al. and Baker et al. clearly anticipate the characteristics of the instant recombinant virus.

Further, the instant claims are drawn to a recombinant virus, which is characterized by complete or partial deletion of a region spanning nucleotides 37391-38239 and up to 43684. Although specific nucleotides are recited, the claim language encompasses nucleotides flanking

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either end of the range as well as any deleted range within the recited range. The claims do not specifically recite which specific partial species the ordinary artisan would immediately envision within the 37391-38239 and up to 43684 ranges. Nonetheless, applicant appears to argue that all of the instant species within the range would be immediately apparent to the ordinary artisan while the species within the range of Baker et al. and Michou et al. would not. It is not apparent how the species for the instant deleted region would be immediately envisioned, but not in the prior art. Contrary to applicant's assertion, the ordinary artisan would be capable of envisioning every part, portion, or species of the CELO DNA region of Baker et al. or Michou et al. In the instant case, it is maintained that the prior art is taught with "sufficient specificity" to constitute anticipation under the statute since the specificities of the instant claims and the prior art are equivalent with respect to the deleted ranges. Therefore, the modified CELO viruses of Michou et al. and Baker et al. comprising a deletion spanning the instant range clearly anticipate the invention. Applicant admits that the instant range is encompassed with within the prior art ranges on page 15 of the response. Therefore, although the teachings of Baker et al. or Michou et al. do not explicitly recite the instant regions, every species of possible deletions is encompassed by "part of" the non-essential region of Baker et al. and the recombinant virus of Michou et al. It is maintained that the references anticipate every element in the claims.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

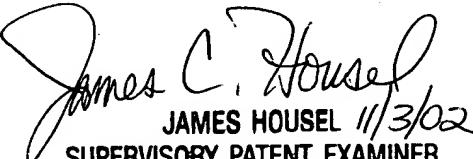
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Shanon Foley  
November 1, 2002

  
JAMES HOUSEL 11/3/02  
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